UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,054	08/25/1999	DAVID A. EDWARDS	AIR-108PA	6042

7590 02/08/2002

CAROLYN S. ELMORE
HAMILTON BROOK SMITH & REYNOLDS P C
TWO MILITIA DRIVE
LEXINGTON, MA 024214799

EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	16

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/383,054	Applicant(s) EDWARDS ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-69,91-108 and 128-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-69,91-108 and 128-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Request for an RCE, the Prior Art Submission, and the Amendment B, all received November 20, 2001.

New Matter

The amendment filed November 20, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

In claims 50, 69, and 91, the phrase "having saturated acyl chains." The passage applicant referred the examiner to (specification, page 10, lines 13-19) did not contain this phrase. Instead it listed specific examples of phospholipids. Therefore, this phrase is not supported by the original disclosure.

In claims 50, 69, and 91, the phrase "having a solute concentration of less than 1 weight/volume percent." The passage applicant referred the examiner to (examples 1 and 2) did not contain this phrase. Instead it specifically stated a solute concentration of 0.1%. Therefore, this phrase is not supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 50-69, 91-108, and 128-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durrani *et al* (hereinafter Durrani). Durrani discloses a process to directly spray dry a drug/lipid powder composition comprising preparing an aqueous solution containing a drug and a lipid containing ethanol solution. The mixture is then spray dried to get particles (p 40, claim 1). Durrani further teach that the drug may be selected from a group which includes insulin, granulocyte colony stimulating factor, interferons, growth factors, calcitonin, and interleukins (p 40, claim 2), as well as peptide hormones, and lung surfactant proteins (p 10-11). Durrani further teaches that the lipid may be selected from the group consisting of phosphatidylglycerol, phosphatidylcholine, phosphatidylinosotil, phosphatidylethanolamines, and phosphatidylserine (p 41, claim 4). Lastly, Durrani teach that the diameter of the resulting particles is between 0.1 and 20 microns (p 14, l 30).

Durrani does not disclose the percent protein integrity of the tap density of the spray dried particles. However, based on the fact that Durrani discloses the same components for the spray dried particles, it is the position of the examiner that the protein integrity and tap density are inherent characteristics, and would be the same as those claimed by applicant, absent the presentation of some unusual and/ or

unexpected results. Further, on page 8 of the specification, applicant states that spray dies particles which have decreased stability are those without a phospholipid or with just an aqueous solvent. Durrani teaches the inclusion of phosphlipids and organic solvents in his particles, so therefore, his particles would have the same improved characteristics as claimed by applicant.

In addition, Durrani does not teach that the phophsolipid be present at 10 weight percent. However, Durrani does not specifiy a specific amount of the ingredients. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

One of ordinary skill in the art would have been motivated to make a spray dried composition of a drug and a lipid based on the generic claim of Durrani. The expected result would be a stable spray dried powder formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments regarding the rejection under 35 U.S.C. 103(a) have been fully considered but are not found persuasive. Applicant has amended the claims to require that the phospholipids have saturated acyl chains. As discussed above, this phrase is deemed new matter. However, the passage referred to by applicant (specification, page 10, lines 13-19) listed specific examples of phospholipids, such as phosphatidylglycerols, phosphatidylcholines, phosphatidylinosotils, phosphatidylethanolamines, and phosphatidylserines. These are examples of phospholipids disclosed by Durrani *et al.*. Therefore, applicant's argument regarding the specific phospholipid is not persuasive.

Applicant further argues that the reference teaches a solids content of 3-4%, whereas applicant claims less than 1%. Again, as discussed above, this limitation is deemed to be new matter. However, applicant has provided no data or evidence to convince the examiner that a difference of 2% solids content renders any unexpected results. Furthermore, it is the position of the examiner that the teachings of Durrani *et al.* achieve the same goal of stability in spray dried powder formulation as applicant is attempting. Therefore, the burden is shifted to applicant to show unexpected results involving only the limitation regarding the solids concentration.

Lastly, applicant has added new claims which require the presence of a buffer. This addition does not render the claims patentable, as Durrani *et al.* teach that if the pH of the solution is a problem, then a buffer salt can be used (p 11, l 19-21).

For these reasons, the rejection under 35 U.S.C. 103(a) is maintained regarding claims 50-69 and 91-108, and is extended to include claims 128-131.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
February 6, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600